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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,907	11/20/2006	Graham Mcintyre	15131.0003	6019

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EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
07/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,907	MCINTYRE ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,13 and 15-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,13 and 15-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22June2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' Response to Office Action, received 22 June 2007, is acknowledged. Claims 1-11, 14, 24, and 25 have been canceled. Claims 12, 13, 15, 16, 17, 19, 22, and 23 have been amended.

2. Claims 12, 13, and 15-23 are pending and under consideration.

Rejections/Objections Withdrawn/Moot

3. The rejection of claims 1-4 under 35 U.S.C. 101 because the claimed recitation of a use, is moot in light of the cancelation of the claims.

4. The rejection of claim 14 under 35 U.S.C. 112, second paragraph, as being indefinite, is moot in light of the cancelation of the claim.

5. The rejection of claim 1-4 under 35 U.S.C. 112, second paragraph, as being indefinite, is moot in light of the cancelation of the claims.

6. The rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Matson et al (U.S. Pat. No. 4,599,310, July, 1986) , is moot in light of the cancelation of the claims.

7. The objection to Figures 3, 4, 5, 6, 7, 8, 9, and 10 under 37 CFR 1.83(a) because they fail to show the units of swelling, is withdrawn in light of the newly submitted replacement drawings.

8. The objection to claim 13 is withdrawn in light of the amendment of the claim.

9. The provisional rejection of claims 12 and 13 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 18 and 19 of copending Application No. 10/526,228, is withdrawn in light of the amendment of the claims.

10. The rejection of claim 14 under 35 U.S.C. 112, first paragraph, scope of enablement for the method for treating or preventing any/all autoimmune diseases or disorders, is moot in light of the cancelation of the claim.

Rejections Maintained

11. The rejection of claims 12, 13, and 15 under 35 U.S.C. 112, first paragraph, scope of enablement for the method for treating or preventing any/all autoimmune diseases or disorders, is maintained for reasons of record.

Applicants argue that a person skilled in the art would understand how to treat or prevent an autoimmune disease or an autoimmune disorder of immunize a sugject aginst an autoimmune disease of an autoimmune disorder by administering the claimed compositions. Applicants included a copy of a soon to be published papter which they indicate supports the enablement of the claims.

The examiner has considered applicants' argument, but does not find it persuasive. The extremely broad scope of the instant claims comprises not only treating, but preventing any/all autoimmune disorders. As stated in the original rejection explanation, the majority of the examples in the specification are drawn to composition preparations and their effect on skin reactions, toxicity, T-cell activity alterations, and immunity inductions. The only examples of treatment present in the specification are drawn to a vascular disease model in rats following angioplasty, and mycarditis.

Thus, the extremely broad scope of the instant claims, i.e., treatment/prevention of all autoimmune disorder constitutes merely an invitation to experiment without a reasonable expectation of success.

New Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Newly amended claims 16-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: 1) methods of altering thickening of the intimal layers of the common carotid artery of rats following balloon angioplasty utilizing injections of *B. bronchialis, R. coprophilus, T. inchonensis, or M. vaccae*, and 2) altering the levels of BCG skin reactions, does not reasonably provide enablement for the extremely broad scope of the instant claims, i.e., method for treating or preventing any/all autoimmune diseases or disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention is method for treating or preventing any/all autoimmune diseases or disorders utilizing injections of *Rhodococcus, Gordonia, Nocardia, Dietzia, Tsukamurella,* and *Nocardioides* whole cell compositions.

The state of the prior art concerning autoimmunity indicates that the mechanisms of occurrence and treatement are multifactorial (Textbook of Medicine, pages 126-163, 15th edition, 1979) and that one composition does not treat or prevent all such immune disorders.

Therefor, there is a lack of predictability in the art that one composition, such as claimed, will treat or prevent any/all autoimmune diseases or autoimmune disorders.

The amount of direction/guidance/examples present in the instant specification is insufficient for the extremely broad scope of the instant claims. The majority of the examples in the specification are drawn to composition preparations and their effect on skin reactions, toxicity, T-cell activity alterations, and immunity inductions. The only examples of treatment present in the specification are drawn to a vascular disease model in rats following angioplasty, and mycarditis.

Thus, the quantity of experimentation necessary for the extremely broad scope of the instant claims constitutes merely an invitation to experiment without a reasonable expectation of success.

Conclusion

14. No claims are allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire

on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

July 12, 2007